

REMARKS/ARGUMENTS

Claims 1-9 were in the application. In the last office action, claims 1-9 were rejected under 35 U.S.C. § 112 for failing to point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-5 and 7-9 were rejected under 35 U.S.C. § 102(b) as anticipated by Plassche, Jr. and, separately, by Gaba,

Claim 6 was rejected under 35 U.S.C. § 103 as obvious over Plassche, Jr. in view of Purdy and, separately, Gaba in view of Purdy.

Claim 1 has amended to overcome the Section 112 rejection and to more clearly distinguish from the Plassche and Gaba references.

Applicant's invention and the inventions disclosed in the cited Plassche and Gaba references seek to permit withdrawal of a needle into a protective enclosure and then prevent the needle from exiting the enclosure. All three devices include a retention device which slidably engages the shank of the needle as it is withdrawn into the protective housing and which moves in front of the point of the needle to block the needle from exiting the protective enclosure. Moreover, all three of the devices provide means for maintaining the retention device in its blocking position once the needle has been fully withdrawn into the protective enclosure.

Plassche and Gaba function in similar ways. Applicant's invention has the following differences. Plassche and Gaba use spring biased devices which are urged against the retention device as the needle is withdrawn into the protective enclosure. Once the

needle clears the retention device, the retention device moves into a position in front of the needle urged by the spring biasing means.

In the embodiment of Figs. 1-14 of Plassche, a retention device (arm 44) is biased against a needle by a hair pin spring 60.

The guard body 38 has a lateral or radially extending L-shaped slot 56 across which the pin 46 extends and pivotally mounts the arm 44 as a rocker arm or lever with portions on opposite sides of the pivot axis defined by the pin 46. One of these portions has a projection 58 in the form of an extension from the lower end thereof which **is biased in blocking relationship with the opening 52 by a hair pin spring 60.** (emphasis added).

Plassche Col. 4, lines 60-67.(See Fig. 8).

In the embodiment of Figs. 15-17 of Plassche, a retention device (arm 106) is biased against a needle by a spring 116.

The arm 106 is biased by a spring 116 which may be a stainless steel strip. The spring 116 biases the projection 110 into interfering relationship with the movement of the stylet 90 across the hole 98 to the position shown in Fig. 17 when the guard body 96 is withdrawn from the hub 80 of the cannula.

Plassche Col. 6, lines 38-43.(See Figs. 15-17).

In the embodiment of Figs. 1-9 of Gaba, a locking arm 246 is biased against a needle by a coil spring 260 to prevent the needle from moving out of a protective housing.

Referring to Figs. 1 and 3, a spring 260 positioned within a spring bore 262 extends to push against a wheel 264, urging the wheel 264 against a ramp 266 on the housing 242, and against the tab 256 on the back end of the locking arm 246.

Gaba Col. 3, lines 41-45.

When the needle assembly 202 is pulled back sufficiently, the point 214 of the needle 212 is pulled within the housing 242, and out of or behind the needle slot 258. As soon as the point 214 clears the needle slot 258, the locking arm 246 springs up (position D in Fig. 9), driven by the spring tension of the locking arm 246 in the housing 242. . . .As the needle slot 258 has shifted upwardly, as shown in Fig. 9, the needle 212 can longer be moved forward out of the housing 242.

Gaba Col. 4, lines 19-26.

In the embodiment of Figs. 10-12 of Gaba, a retainer 302 is biased against a needle by a coil spring 260 to prevent the needle from moving out of a protective housing as in the previous embodiment.

Referring to Fig. 11, when the point 135 of the needle 132 moves behind the front slot 316, the retainer 302 pivots upwardly [urged by the force of the spring 260 - see Figs. 10-11], releasing the hook 314 from the catheter 222. . . .The needle cannot be pushed forward out of the housing 320 as the front housing opening 328 is now blocked by the front leg 318 of the retainer 302.

Gaba Col. 5, lines 22-37.

In the embodiment of Figs. 13-15 of Gaba, a spring 352 urges a retainer 348 against a needle and, when the needle is withdrawn, blocks the needle to prevent it from moving out of a protective housing.

A retainer 348 has a hook 354 extending out of the housing 344 to engage and hold the catheter to the housing. A spring 352 urges the retainer 348 to the rear of the housing 344.

Gaba Col. 5, lines 52-55.

In the embodiment of Figs. 16-20 of Gaba, a spring 400 urges a needle into a protective housing.

The spring drives the slide 390 rearwardly to automatically withdraw the point 135 of the needle into the housing 380, where the needle may be safely contained for handling and disposal. . .

Gaba Col. 6, lines 31-34.

In applicant's invention, there are no springs or other biasing devices to urge the retention device 6 against the needle or into a needle blocking position. As stated in the specification at page 6, lines 18-24:

After skin puncture and insertion of the catheter into the vein, the needle is withdrawn and its end arrives in the 20 cage as it emerges from the device (figures 4 and 5).

The device, which is no longer held by the needle, **tilts of its own accord** (figures 6 and 7), and its flexible tongue (6d) deploys under the lateral wall of the cage (5), preventing reverse tilting of the device. (emphasis added).

Thus it is seen that applicant's retention device 6 "tilts of its own accord", i.e., under its own weight. See original claim 2. There are no springs or other external components to bias applicant's retention device toward a needle blocking position.

It is to be further noted that in Plassche and Gaba, the same spring biasing means which urges the retention device into a blocking position resists movement of the retention device from the blocking position. This approach taken by Plassche and Gaba, has at least two disadvantages.

First, the biasing spring which urges the retention device against the shank of the needle causes an increase in friction between the retention device and the needle which interferes with the withdrawal of the needle from the patient. The force needed to overcome the friction can cause discomfort and even pain to the patient.

Second, dependence on the biasing force of the spring to prevent return of the retention device to a position which would permit the needle to exit the enclosure may not provide sufficient protection. While in a blocking position, the retention device can be moved if sufficient force is exerted to overcome the spring bias.

Applicant overcomes the foregoing disadvantages of Plassche and Gaba as follows. As applicants retention device drops into its needle blocking position, a flexible tongue 6d on the end of the retention device 6 is captured under a lateral wall of the cage 5 thereby preventing reversed tilting of the device. See page 6, lines 21-24. No force need be continuously exerted on the retention device to prevent it from moving to an unsafe position.

Claim 1 has been amended to more clearly distinguish from the cited references and now recites:

this dog is formed at one end (6a) of a retention device (6) mounted to tilt **on its own, unbiased by any other force-producing component**, from a position permitting withdrawal of said needle into said cage to a position blocking exit of said needle from said cage, around a pivoting axis which is transverse to the sliding direction of the needle, the said device having one opposite end (6b) in lateral contact with the needle,

the only friction between said needle and said opposite end of said device when the latter traverses the cage being due to the weight of said one end of said device. . . (emphasis added).

Support for the amendment is found in the specification at page 6, lines 18-24, and in Figs. 5-8 of the drawings. See also, original claim 2.

Accordingly, claim 1 is now believed to be patentable over the art of record. Claims 2-9 depend from claim 1 and are, therefore, also believed to now be patentable.

In rejecting claim 5, the Examiner likened the leaf spring of Plassche and the coil spring of Gaba to tongues. Claim 5 has been amended to recite that the tongue is integral and moves with the retention device. Hence, in addition to its dependence on claim 1, claim 5 is believed to be patentable for the reason stated immediately above.

In view of the foregoing, it is respectfully submitted that the application is now in condition for allowance. Early and favorable action is earnestly solicited.

An unpaid fee required to keep this case alive may be charged to deposit account 06-0735.

Respectfully Submitted,

/Howard F. Mandelbaum/
Howard F. Mandelbaum
Registration No. 27,519
Attorney for Applicant

HFM:tct